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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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14 IN RE FIBROGEN, INC., SECURITIES
LITIGATION

Case No. 3:21-cv-02623-EMC

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CLASS ACTION

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**REQUEST FOR JUDICIAL NOTICE AND
CONSIDERATION OF DOCUMENTS
INCORPORATED BY REFERENCE IN
SUPPORT OF DEFENDANTS' MOTION TO
DISMISS PLAINTIFFS' CONSOLIDATED
CLASS ACTION COMPLAINT**

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Hearing Date: April 28, 2022
Time: 1:30 pm
Courtroom: 5
Judge: Hon. Edward M. Chen

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1 **I. INTRODUCTION**

2 Defendants FibroGen, Inc. (“FibroGen” or the “Company”), and Enrique Conterno, James
 3 Schoeneck, Mark Eisner, and Pat Cotroneo (collectively, “Defendants”) respectfully request that
 4 the Court consider under the incorporation by reference doctrine and/or take judicial notice of the
 5 exhibits identified below in support of Defendants’ concurrently filed Motion to Dismiss the
 6 Consolidated Class Action Complaint (the “Motion”). All exhibits are attached to the Declaration
 7 of Alexander J. Kasner in Support of Defendants’ Motion to Dismiss Plaintiffs’ Consolidated Class
 8 Action Complaint and Request for Judicial Notice and Consideration of Documents Incorporated
 9 by Reference (“Kasner Declaration”), filed concurrently herewith.

10 The Court should consider Exhibits A-HHH attached to the Kasner Declaration because
 11 they provide the context the Supreme Court requires this Court to consider in evaluating whether
 12 Plaintiffs have adequately pleaded a securities fraud claim. *Tellabs, Inc. v. Makor Issues & Rights,*
 13 *Ltd.*, 551 U.S. 308, 322 (2007). 43 of the 57 exhibits are referenced in the Consolidated Class
 14 Action Complaint (the “CAC”) and form the basis of Plaintiffs’ claims, such that they are properly
 15 deemed incorporated by reference. Defendants understand that this is a significant number of
 16 documents, are mindful about burdening the Court with such volume of information, and do not
 17 make this Request without careful consideration. However, Plaintiffs challenge nearly 100 separate
 18 statements over an almost three-year period, that come from 37 sources. Including all of these 37
 19 documents that Plaintiffs claim contain false or misleading statements is necessary to allow the
 20 Court to view each alleged misstatement in context. Another six documents form the basis of
 21 Plaintiffs’ claims and are therefore incorporated by reference. Finally, 14 of the documents are the
 22 proper subject of judicial notice.¹ The Court is required under *Tellabs* to consider these documents
 23 in evaluating the adequacy of the CAC. An index identifying the documents subject to this request
 24 and the bases for considering them is included below.

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¹ In addition to being incorporated by reference, the 43 documents referenced in the CAC, 37 of
 28 which contain the alleged false or misleading statements, are *also* properly the subject of judicial
 notice, and the Court may also consider them for that reason.

1 **II. DOCUMENTS SUBJECT TO THIS REQUEST²**

| Exhibit | Description | Basis | ¶¶ |
|----------|--|------------|--------------------------|
| A | FibroGen's Form 10-K for the fiscal year 2017, filed with the SEC on February 27, 2018 | JN | |
| B | Statistical Analysis Plan, dated August 2, 2018, for Study 608 of Patients not on dialysis, available on ClinicalTrials.gov | JN | |
| C | Statistical Analysis Plan, dated September 28, 2018, for Study 002 of Dialysis Patients, available on Clinical Trials.gov | JN | |
| D | Statistical Analysis Plan, dated October 14, 2018, for Study 063 of Incident Dialysis Patients, available on Clinical Trials.gov | JN | |
| E | FibroGen's press release titled <i>FibroGen Announces Positive Topline Results from Three Global Phase 3 Trials of Roxadustat for Treatment of Anemia in Patients with Chronic Kidney Disease</i> , published on FibroGen's website on December 20, 2018 | IBR, JN | 51, 142-44 |
| F | AstraZeneca's press release titled <i>AstraZeneca Announces Phase III OLYMPUS and ROCKIES trials for Roxadustat met their primary endpoints in CKD patients with anaemia</i> , published on AstraZeneca's website December 20, 2018 | JN | |
| G | Transcript of FibroGen's Earnings Call for the fourth quarter of 2018 ("Q4 2018") on February 27, 2019, published by S&P Global Market Intelligence | IBR, JN | 145-46 |
| H | FibroGen's Form 10-K for 2018, filed with the SEC on February 27, 2019 | JN | |
| I | FibroGen's press release titled, <i>FibroGen Announces Positive Topline Results from Pooled Safety Analyses of Roxadustat Global Phase 3 Program</i> , published on FibroGen's website May 9, 2019 | IBR, JN | 53, 147-52, 263 |
| J | Transcript of FibroGen's Earnings Call for the first quarter of 2019 ("Q1 2019") on May 9, 2019, published by S&P Global Market Intelligence | IBR, JN | 5, 53, 54, 55, 153-61 |
| K | Jefferies Report titled <i>We spoke with mgmt, Roxa event rates are lower (+) - stock should rebound</i> , published on May 9, 2019 | IBR, JN | 56 |

27 ² "Exhibit" refers to the exhibits to the Kasner Declaration. "Basis" refers to the reason the
28 document should be considered: either incorporated by reference ("IBR") or judicial notice ("JN").
"¶¶" refers to the paragraphs of the CAC that cite or reference the document.

| Exhibit | Description | Basis | ¶¶ |
|----------|---|---------|---------------------|
| L | FibroGen's Form 10-Q for the first quarter of 2019 ("Q1 2019"), filed with the SEC on May 9, 2019 | IBR, JN | 37, 162 |
| M | Transcript of FibroGen's presentation at the 40th Annual Goldman Sachs Global Healthcare Conference on June 12, 2019, published by S&P Global Market Intelligence | IBR, JN | 57, 163-66 |
| N | Transcript of FibroGen's Earnings Call for the second quarter of 2019 ("Q2 2019") on August 8, 2019, published by S&P Global Market Intelligence | IBR, JN | 59, 167-68, 170 |
| O | FibroGen's Form 10-Q for the second quarter of 2019 ("Q2 2019"), filed with the SEC on August 9, 2019 | IBR, JN | 169-70 |
| P | FibroGen's press release titled, <i>FibroGen Announces Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results for Treatment of Anemia in Chronic Kidney Disease</i> , published on FibroGen's website November 8, 2019 | IBR, JN | 61-63, 171-75 |
| Q | AstraZeneca's press release titled <i>AstraZeneca Announces Roxadustat Phase III programme pooled analyses showed positive efficacy and no increased cardiovascular risk in patients with anaemia from chronic kidney disease</i> , published on AstraZeneca's website November 8, 2019 | JN | |
| R | Transcript of FibroGen's Earnings Call for the third quarter of 2019 ("Q3 2019") on November 11, 2019, published by S&P Global Market Intelligence | IBR, JN | 22, 64, 177-78, 248 |
| S | FibroGen's Form 10-Q for the third quarter of 2019 ("Q3 2019"), filed with the SEC on November 12, 2019 | IBR, JN | 22, 181-83 |
| T | BuyersStrike! Article titled <i>Victory Lap Re-up: What's harder to find, the PYRENEES data set in an FGEN presentation, or an Andorra on a map?</i> , published on November 14, 2019 | IBR, JN | 179, 182-83 |
| U | Transcript of FibroGen's presentation at the 9th Annual SVB Leerink Global Healthcare Conference on February 25, 2020, published by S&P Global Market Intelligence | IBR, JN | 67, 184-86 |
| V | Transcript of FibroGen's Earnings Call for the fourth quarter of 2019 ("Q4 2019") on March 2, 2020, published by S&P Global Market Intelligence | IBR, JN | 187-88 |
| W | FibroGen's Form 10-K for 2019, filed with the SEC on March 2, 2020 | IBR, JN | 187-88 |

| 1 | Exhibit | Description | Basis | ¶¶ |
|----|----------------|---|--------------|-------------------|
| 2 | X | Transcript of FibroGen's Earnings Call for the first quarter of 2020 ("Q1 2020") on May 7, 2020, published by S&P Global Market Intelligence | IBR, JN | 189, 191 |
| 3 | Y | Transcript of FibroGen's presentation at Bank of America Securities 2020 HealthCare Conference on May 14, 2020, published by S&P Global Market Intelligence | IBR, JN | 68, 190-91 |
| 4 | Z | Transcript of FibroGen's presentation at Jefferies Healthcare Conference on June 2, 2020, published by Thomson Reuters | IBR, JN | 192, 194 |
| 5 | AA | Transcript of FibroGen's 2020 Annual Meeting of Shareholders on June 4, 2020, published by S&P Global Market Intelligence | IBR, JN | 193-94 |
| 6 | BB | Transcript of FibroGen's presentation at Goldman Sachs 41st Annual Global Healthcare Conference on June 9, 2020, published by S&P Global Market Intelligence | IBR, JN | 5, 68, 195-97 |
| 7 | CC | Transcript of FibroGen's Earnings Call for the second fiscal quarter of 2020 ("Q2 2020") on August 6, 2020, published by S&P Global Market Intelligence | IBR, JN | 198, 200 |
| 8 | DD | FibroGen's Form 10-Q for the second quarter of 2020 ("Q2 2020"), filed with the SEC on August 6, 2020 | IBR, JN | 20, 199-200 |
| 9 | EE | Transcript of FibroGen's presentation at Citi 15th Annual Biopharma Virtual Conference on September 9, 2020, published by S&P Global Market Intelligence | IBR, JN | 69, 201, 203, 204 |
| 10 | FF | Transcript of FibroGen's presentation at Morgan Stanley 18th Annual Global Healthcare Conference on September 16, 2020, published by S&P Global Market Intelligence | IBR, JN | 202-04 |
| 11 | GG | Transcript of FibroGen's Earnings Call for the third quarter of 2020 ("Q3 2020") on November 5, 2020, published by S&P Global Market Intelligence | IBR, JN | 205-06 |
| 12 | HH | Transcript of FibroGen's presentation at Stifel Virtual Healthcare Conference on November 17, 2020 | IBR, JN | 207, 209 |
| 13 | II | Transcript of FibroGen's presentation at Jefferies 2020 Virtual London Healthcare Conference on November 19, 2020, published by S&P Global Market Intelligence | IBR, JN | 5, 69, 208-09 |
| 14 | JJ | FibroGen's press release titled, <i>FibroGen Announces Retirement of K. Peony Yu, M.D., and Appointment of Mark Eisner, M.D., M.P.H. as Chief Medical Officer</i> , published on FibroGen's website on December 1, 2020 | IBR, JN | 23, 72, 258 |
| 15 | KK | Letter from R. Wayne Frost, Senior Vice President, FibroGen to the FDA Regarding a Citizen Petition by | IBR, JN | 211-15, 248 |

| 1 | Exhibit | Description | Basis | ¶¶ |
|----|-----------|--|------------|-------------------------------|
| 2 | | Epstein Becker & Green Regarding the Pending New Drug Application for Roxadustat, dated December 9, 2020, published on December 10, 2020 on Regulations.gov | | |
| 3 | LL | FibroGen's press release titled, <i>FibroGen Provides Regulatory Update on Roxadustat</i> , published on FibroGen's website March 1, 2021 | IBR, JN | 8, 74, 216-17, 264 |
| 4 | MM | Transcript of FibroGen's Earnings Call for the fourth quarter of 2020 ("Q4 2020") on March 1, 2021, published by S&P Global Market Intelligence | IBR, JN | 76, 218 |
| 5 | NN | FibroGen's Form 10-K for 2020, filed with the SEC on March 1, 2021 | IBR, JN | 38, 43, 44, 256 |
| 6 | OO | Transcript of FibroGen's presentation at Cowen 41st Annual Health Care Conference on March 2, 2021, published by S&P Global Market Intelligence | IBR, JN | 219-20 |
| 7 | PP | FibroGen's press release titled, <i>FibroGen Provides Additional Information On Roxadustat</i> , published on FibroGen's website April 6, 2021 | IBR, JN | 222, 227-29, <i>passim</i> |
| 8 | QQ | Transcript of FibroGen's Special Call on April 6, 2021, published by S&P Global Market Intelligence | IBR, JN | 223-29 |
| 9 | RR | Transcript of FibroGen's Earnings Call for the first quarter of 2021 ("Q1 2021") on May 10, 2021, published by S&P Global Market Intelligence | IBR, JN | 230, 232 |
| 10 | SS | Transcript of FibroGen's presentation at Bank of America Securities 2021 Virtual Health Care Conference on May 13, 2021, published by S&P Global Market Intelligence | IBR, JN | 231-32 |
| 11 | TT | Transcript of FibroGen's presentation at Jefferies 2021 Virtual Healthcare Conference on June 4, 2021, published by S&P Global Market Intelligence | IBR, JN | 233, 235 |
| 12 | UU | Transcript of FibroGen's presentation at Goldman Sachs 42nd Annual Global Healthcare Conference on June 10, 2021, published by S&P Global Market Intelligence | IBR, JN | 234-35 |
| 13 | VV | FDA Advisory Committee Materials titled, <i>FDA Briefing Information for the July 15, 2021 Meeting of the Cardiovascular and Renal Drugs Advisory Committee</i> , published on July 13, 2021 and publicly available at https://www.fda.gov/media/150728/download | IBR, JN | 103-04, 228 |
| 14 | WW | FDA Advisory Committee Materials titled, <i>FibroGen Briefing Information for the July 15, 2021 Meeting of the Cardiovascular and Renal Drugs Advisory Committee</i> , | JN | |
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| Exhibit | Description | Basis | ¶¶ |
|------------|---|------------|------------------|
| | published on July 13, 2021 and publicly available at https://www.fda.gov/media/150730/download | | |
| XX | FDA Advisory Committee Document titled, <i>Transcript for the July 15, 2021 Meeting of the Cardiovascular and Renal Drugs Advisory Committee</i> , and publicly available at https://www.fda.gov/media/152124/download | IBR, JN | 105, 106, 108-09 |
| YY | FibroGen's Form 10-Q for the second quarter of 2021 ("Q2 2021"), filed with the SEC on August 9, 2021 | IBR, JN | 256 |
| ZZ | Astellas's press release titled <i>Astellas Receives European Commission Approval for First-in-Class EVRENZO (roxadustat) for Adult Patients with Symptomatic Anemia of Chronic Kidney Disease</i> , published on Astellas's website on August 19, 2021 (https://newsroom.astellas.us/2021-08-19-Astellas-Receives-European-Commission-Approval-for-First-in-Class-EVRENZO-TM-roxadustat-for-Adult-Patients-with-Symptomatic-Anemia-of-Chronic-Kidney-Disease ; https://investor.fibrogen.com/news-releases/news-release-details/astellas-receives-european-commission-approval-first-class) | JN | |
| AAA | FibroGen's Form 4s reporting Changes in Beneficial Ownership for Dr. Peony Yu, filed with the SEC between May 20, 2016 and December 17, 2020, to the extent those Form 4s reflect the sale and/or disposition of stock | JN | |
| BBB | FibroGen's Form 4s reporting Changes in Beneficial Ownership for Enrique Conterno, filed with the SEC between May 20, 2016 and July 15, 2021, to the extent those Form 4s reflect the sale and/or disposition of stock | JN | |
| CCC | FibroGen's Form 4s reporting Changes in Beneficial Ownership for Pat Cotroneo, filed with the SEC between May 20, 2016 and July 15, 2021, to the extent those Form 4s reflect the sale and/or disposition of stock | JN | |
| DDD | FibroGen's Form 4s reporting Changes in Beneficial Ownership for James Schoeneck, filed with the SEC between May 20, 2016 and July 15, 2021, to the extent those Form 4s reflect the sale and/or disposition of stock | JN | |
| EEE | FibroGen's Form 4s reporting Changes in Beneficial Ownership for Thomas Neff, filed with the SEC between May 20, 2016 and August 22, 2019, to the extent those Form 4s reflect the sale and/or disposition of stock | JN | |

1 **III. ARGUMENT**

2 In determining whether Plaintiffs' CAC satisfies the strict pleading burden of the PSLRA,
 3 the Court "must consider the complaint in its entirety, as well as other sources courts ordinarily
 4 examine when ruling on 12(b)(6) motions to dismiss, in particular, documents incorporated into the
 5 complaint by reference, and matters of which a court may take judicial notice." *Tellabs*, 551 U.S.
 6 at 322. Consistent with the Supreme Court's mandate in *Tellabs*, the Court here should consider
 7 Exhibits A through HHH in deciding the Motion to Dismiss.

8 Exhibits E, G, I-P, R-VV, and XX-YY are incorporated by reference in the CAC, as
 9 Plaintiffs either reference their contents or quote portions of the documents to support their claims
 10 and allegations. These documents include press releases issued by FibroGen, transcripts of
 11 FibroGen's earnings calls and presentations at analyst conferences, filings with the Securities and
 12 Exchange Commission ("SEC"), analyst reports, and documents generated by or in connection with
 13 U.S. Food and Drug Administration ("FDA") regulatory activities. The Court may also take
 14 judicial notice of these documents that are incorporated by reference into the CAC.

15 Further, judicial notice of Exhibits A-D, F, H, Q, WW, and ZZ-EEE is proper pursuant to
 16 Federal Rule of Evidence 201, which allows the Court to take judicial notice of certain publicly
 17 available and accurate information that is not the subject of reasonable dispute. These include
 18 FibroGen's public filings with the SEC, statements of changes in beneficial ownership of FibroGen
 19 securities filed with the SEC on Form 4, publicly available documents published by the FDA or
 20 submitted to the FDA and available on a publicly available websites affiliated with a government
 21 agency, and press releases from FibroGen's partners AstraZeneca plc and Astellas Pharma Inc.
 22 publicly available on those company's websites. These documents are critical to the Court's
 23 assessment of Plaintiffs' claim that Defendants committed securities fraud.

24 **A. The Court Should Deem the Documents Plaintiffs Refer to and Rely upon to
 25 Be Incorporated by Reference into the Amended Complaint.**

26 A document is incorporated by reference into a complaint "if the plaintiff refers extensively
 27 to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*,
 28 342 F.3d 903, 908 (9th Cir. 2003). Even where a plaintiff references only a short excerpt of the

1 document, the document may be incorporated by reference if the plaintiff's "claim necessarily
 2 depend[s] on [the document]." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1002 (9th Cir.
 3 2018). The incorporation by reference doctrine exists to "prevent[] plaintiffs from selecting only
 4 portions of documents that support their claims, while omitting portions of those very documents
 5 that weaken—or doom—their claims." *Id.* "Once a document is deemed incorporated by reference,
 6 the entire document is assumed to be true for the purposes of a motion to dismiss, and both parties—
 7 and the Court—are free to refer to any of its contents." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d
 8 1046, 1058 n.10 (9th Cir. 2014) (citation omitted).

9 The Court should consider Exhibits E, G, I-P, R-VV, and XX-YY under the incorporation
 10 by reference doctrine because the content of each document is either referenced, paraphrased, or
 11 quoted in the CAC and, accordingly, each document forms the basis for Plaintiffs' claims. *See*
 12 *Ritchie*, 342 F.3d at 908. Plaintiffs admit that their allegations are based on "public filings [by
 13 FibroGen] with the Securities and Exchange Commission," "information concerning FibroGen
 14 from the U.S. Food and Drug Administration," "reports" from "analysts concerning FibroGen,"
 15 "transcripts of FibroGen's conference calls," and "presentations, press releases, and media reports
 16 regarding FibroGen." (¶ 1.) They cite, quote, or reference these documents throughout the CAC.
 17 Defendants provide the full text (or substantial, relevant excerpts) of each document so the Court
 18 is able to consider Plaintiffs' citations and allegations in context. *See, e.g., In re Silicon Storage*
 19 *Tech., Inc. Sec. Litig.*, 2006 WL 648683, at *2 (N.D. Cal. Mar. 10, 2006) ("If a plaintiff fails to
 20 attach to the complaint the documents on which it is based, defendant may attach to a Rule 12(b)(6)
 21 motion the documents referred to in the complaint to show that they do not support plaintiff's
 22 claim.")

23 **1. Exhibits forming the basis of Plaintiffs' false and misleading statement
 24 allegations.**

25 **Documents Containing the Alleged false and misleading statements:**

26 Exhibits E, G, I, J, L-P, R, S, T-II, KK-MM, and OO-UU contain the 96 statements that
 27 Plaintiffs contend are false and misleading.

28

- Exhibits M, U, Y, Z, BB, EE-FF, HH-II, OO, and SS-UU are transcripts of FibroGen's presentations at various investor conferences during the Class Period. Plaintiffs allege that Defendants made false and misleading statements at these conferences. (¶¶ 163-66; 184-86; 190-97, 201-04, 207-09, 218-20, 231-35.)
- Exhibits G, J, N, R, V, X, CC, GG, MM, QQ, and RR are transcripts of FibroGen quarterly earnings calls and other special investor conference calls. Plaintiffs allege that Defendants made false and misleading statements during these conference calls. (¶¶ 145-46, 153-61, 167-70, 177-80, 187-91, 193-94, 198-200, 205-06, 218-20, 223-29, 230-32.)
- Exhibits E, I, P, LL, and PP are FibroGen press releases issued during the Class Period. Plaintiffs allege that Defendants made false and misleading statements in these press releases. (¶¶ 142-44, 147-50, 171-75, 216-17, 227-29.)
- Exhibits L, O, S, W, DD, and YY are relevant excerpts of FibroGen SEC filings made during the Class Period. Plaintiffs allege as false and misleading statements made in these filings. (¶¶ 66, 162, 169-70, 181-83, 199-200.)
- Exhibit T is a November 14, 2019 report published by BuyersStrike!, an online blog containing investment recommendations. Plaintiffs allege as false and misleading statements attributed to FibroGen, that were quoted in this report. (¶ 179.)
- Exhibit KK is a December 9, 2020 letter from FibroGen Senior Vice President Frost to the FDA. Plaintiffs allege that false and misleading statements were made in this letter. (¶¶ 211-15.)

As the alleged false and misleading statements must be considered in context, *Khoja*, 899 F.3d at 1002, these documents are incorporated by reference into the CAC and should be considered by the Court in their entirety. *Park v. GoPro, Inc.*, 2019 WL 1231175, at *6 (N.D. Cal. Mar. 15, 2019) (incorporating by reference press release and Form 10-Q that contained “[s]everal of the allegedly false statements”).

Sources Referenced in CAC Purportedly to support falsity: The CAC references several documents that, while not containing the allegedly false and misleading statements, nevertheless form the basis for Plaintiffs' claims as Plaintiffs rely upon them to plead falsity under the PSLRA. These too should be incorporated by reference. *Smith v. NetApp, Inc.*, 2021 WL 1233354, at *3 (N.D. Cal. Feb. 1, 2021) (holding documents “are properly incorporated by reference because Plaintiff uses them to demonstrate falsity”).

1 Exhibit K is a Jeffries analyst report that Plaintiffs quote or paraphrase in the CAC to allege
 2 the falsity of FibroGen statements challenged in the CAC. (¶ 56 (quoting from Ex. K to assert that
 3 “FibroGen sought to strongly reassure the market that Roxadustat’s MACE safety data supported
 4 FDA approval”).)

5 Exhibits VV and XX consist of materials from the FDA Advisory Committee that Plaintiffs
 6 likewise quote or paraphrase in the CAC to allege the falsity of FibroGen statements challenged in
 7 the CAC. For example, the CAC quotes materials prepared and published by the FDA in
 8 connection with its July 15, 2021 Advisory Committee meeting (Ex. VV) to purport to show the
 9 risks associated with roxadustat’s safety data. (¶¶ 104-06.) Likewise, Plaintiffs cite excerpts from
 10 the transcript of that FDA Advisory Committee meeting (Ex. XX) to argue that “Defendants’
 11 positive Class Period statements concerning the drug’s safety and efficacy were demonstrably
 12 false.” (¶¶ 108-09.)

13 Plaintiffs appear to rely on Exhibits K, VV, and XX in an attempt to meet their burden of
 14 pleading falsity “with particularity,” which requires “specify[ing] each statement alleged to have
 15 been misleading, [and] the reason or reasons why the statement is misleading.” *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990-91 (9th Cir. 2009). As these documents form the basis
 16 for Plaintiffs’ claims, they should be deemed incorporated by referenced into the CAC.

17 **2. Exhibits forming a basis for Plaintiffs’ scienter allegations.**

18 To plead a violation of Section 10(b), the Plaintiffs must “state with particularity facts
 19 giving rise to a strong inference that the defendant” made allegedly misleading statements “either
 20 intentionally or with deliberate recklessness.” *Zucco*, 552 F.3d at 991. Plaintiffs refer to and quote
 21 Exhibits JJ, NN, PP, QQ, VV, XX, and YY, claiming that these documents support their allegations
 22 that Defendants acted with scienter. In particular, Plaintiffs paraphrase the content of press releases
 23 issued by FibroGen (Exs. JJ, PP), allegedly to show that Defendants withheld information from the
 24 market. (¶¶ 249, 258.) Plaintiffs likewise paraphrase the transcript of a FibroGen special investor
 25 call (Ex. QQ) to argue that Defendants “did not themselves reveal the full truth” of the safety data.
 26 (¶ 249.) Plaintiffs cite information from FibroGen’s Form 10-Q for the second quarter of 2021 (Ex.
 27 YY) regarding milestone payments to which the Company may be entitled as a purported motive

1 to commit fraud. (¶ 256.) Thus, as Plaintiffs rely on these documents in an effort to meet their
 2 burden to plead scienter, they form the basis of Plaintiffs' claims and are incorporated by reference
 3 into the CAC. *Tellabs*, 551 U.S. at 322-23; *see also In re SunPower Corp. Sec. Litig.*, 2018 WL
 4 4904904, at *3 n.2 (N.D. Cal. Oct. 9, 2018) (incorporating exhibits by reference because Plaintiffs
 5 referred to them “explicitly as the ground for [the company’s] false statements and scienter”).

6 **B. The Court Should Take Judicial Notice of All Documents Submitted by
 7 Defendants.**

8 Courts may take judicial notice of a fact that is “not subject to reasonable dispute because
 9 it: (1) is generally known within the trial court’s territorial jurisdiction; or (2) can be accurately and
 10 readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid.
 11 201(b). Unlike documents incorporated by reference, judicial notice extends to “matters of public
 12 record *outside* the pleadings.” *Plevy v. Haggerty*, 38 F. Supp. 2d 816, 820 (C.D. Cal. 1998)
 13 (emphasis added). Courts routinely take judicial notice of SEC filings, analyst reports, and other
 14 public information for the purpose of showing what information was available to the stock market
 15 and when. *See In re Apple Inc. Sec. Litig.*, 2020 WL 2857397, at *6 (N.D. Cal. June 2, 2020).

16 **1. The Court Should Take Judicial Notice of All Documents that Are
 17 Referenced by the Complaint and Therefore Incorporated by
 18 Reference.**

19 All the documents which Defendants ask the Court to incorporate by reference are also
 20 properly subject to judicial notice. As SEC filings, Exhibits L, O, S, W, DD, NN, and YY are
 21 subject to judicial notice. *See, e.g., Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049,
 22 1064 n.7 (9th Cir. 2008). Judicial notice of documents filed publicly with the SEC “for the purpose
 23 of determining what was disclosed to the market” is appropriate. *In re Aqua Metals, Inc. Sec. Litig.*,
 24 2019 WL 3817849, at *5 (N.D. Cal. Aug. 14, 2019) (taking judicial notice of SEC filings and press
 25 releases). So too are press releases and conference and earnings call transcripts (Exs. E, G, I-J, M-
 26 N, P, R, U-V, X-CC, EE-JJ, LL, MM, OO, PP, QQ-UU), “because the[y] are relied on extensively
 27 by Plaintiffs and are used as evidence to establish a material misstatement or omission” and “are
 28 also matters of public record.” *In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 827 (N.D. Cal. 2019); *see also Azar v. Yelp, Inc.*, 2018 WL 6182756, at *3, *5 (N.D. Cal. Nov. 27, 2018)

1 (granting judicial notice of transcript of a presentation at an investment bank conference where
 2 plaintiffs quoted it six times in complaint). And the analyst reports or blog posts (Exs. K, T) that
 3 Plaintiffs rely upon are also judicially noticeable. *Yaron v. Intersect ENT, Inc.*, 2020 WL 6750568,
 4 at *4 (N.D. Cal. June 19, 2020) (granting judicial notice of analyst report “not for the truth of [its]
 5 contents, but to determine the information available to the market”).

6 **2. The Court Should Take Judicial Notice of Other, Publicly Available
 7 Documents**

8 In addition, several exhibits that were not cited in the CAC are also subject to judicial notice
 9 and their contents should be considered by the Court in ruling on the Motion. These include: (1)
 10 FibroGen’s public filings with the SEC (Exs. A, H); (2) statements of changes in beneficial
 11 ownership of FibroGen securities filed with the SEC on Form 4 (Exs. AAA-EEE); (3) publicly
 12 available documents published by the FDA or submitted to the FDA and available on government-
 13 affiliated websites (Exs. B-D, WW); and (4) press releases from AstraZeneca and Astellas that are
 14 publicly available on those company’s websites. (Exs. F, Q, ZZ). Judicial notice is proper to
 15 “indicate what was in the public realm at the time, not whether the contents of those [documents]
 16 were in fact true.” *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th
 17 Cir. 2010) (citation omitted).

18 **SEC Filings.** The Court should take judicial notice of several of FibroGen’s public filings
 19 with the SEC, in particular, FibroGen’s annual reports on Form 10-K for 2017 and 2018 (Exs. A,
 20 H). Judicial notice of these materials “for the purpose of determining what was disclosed to the
 21 market” is appropriate. *In re Aqua Metals*, 2019 WL 3817849, at *5 (taking judicial notice of SEC
 22 filings and press releases). Indeed, in securities fraud cases, courts routinely take judicial notice of
 23 publicly available SEC filings. *See, e.g., Welgus v. TriNet Grp., Inc.*, 2017 WL 6466264, at *5
 24 (N.D. Cal. Dec. 18, 2017) (taking notice of SEC filings, including Form 10-K, for “the fact of their
 25 existence, and not of the truth of the matters asserted therein”).

26 **Form 4s.** The Court should take judicial notice of Exhibits AAA-EEE, which are all the
 27 Form 4s filed with the SEC that report the purchase or sale of securities by the Individual
 28

1 Defendants and non-Defendant Thomas Neff during the Class Period. The contents of each Exhibit
 2 are as follows:

- 3 • Exhibit AAA compiles all the Form 4s reflecting sales for Dr. Peony Yu between May
 4 20, 2016 and December 17, 2020.
- 5 • Exhibit BBB compiles all the Form 4s reflecting open-market stock purchases for
 6 Enrique Conterno between May 20, 2016 and July 15, 2021.
- 7 • Exhibit CCC compiles all the Form 4s reflecting sales for Pat Cotroneo between May
 8 20, 2016 and July 15, 2021.
- 9 • Exhibit DDD compiles all the Form 4s reflecting sales for James Schoeneck between May
 10 20, 2016 and July 15, 2021.
- 11 • Exhibit EEE compiles all the Form 4s reflecting sales for Thomas Neff between May
 12 20, 2016 and August 22, 2019.³

13 Plaintiffs allege that “the Individual Defendants engaged in substantial and coordinated
 14 stock sales” during the Class Period that support scienter. (¶ 253; *see also* ¶¶ 134-39.) Stock sale
 15 information is publicly available through Form 4s, which are proper subjects of judicial notice,
 16 particularly where Plaintiffs’ “scienter . . . allegations do rely expressly on . . . stock sales.” *City*
 17 *of Royal Oak Retirement Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1059 (N.D. Cal.
 18 2012) (taking judicial notice of Form 4s, including “to prove that stock sales were made pursuant
 19 to a Rule 10b5-1 trading plan”).

20 **Publicly Available FDA Documents.** Defendants ask the Court to take judicial notice of
 21 publicly available documents created by or submitted to the FDA. This includes Statistical
 22 Analysis Plan (“SAP”) documents submitted by FibroGen to the FDA and publicly available on
 23 the website of the National Library of Medicine, a division within the National Institutes of Health
 24 (Exs. B-D). The SAPs describe in detail the planned statistical analyses for the clinical trials
 25 discussed at length in the CAC, and are available on public websites maintained by the government.
 26 *See, e.g., Crihfield v. CytRx Corp.*, 2017 WL 2819834, at *1 (C.D. Cal. June 14, 2017) (taking
 27 judicial notice of Special Protocol Assessment agreement with FDA, “regarding the design,
 28 endpoints and planned statistical approach of [a] Phase 3 clinical trial”).

29
 30 ³ Though Neff is not named as an Individual Defendant, Plaintiffs cite Neff’s stock sales during the
 31 Class Period in an attempt to allege scienter. (¶¶ 135, 137, 253.)

The Court should also take judicial notice of briefing materials prepared by FibroGen and published on the FDA website for use in connection with the Advisory Committee meeting held on July 15, 2021 (Ex. WW). The CAC refers extensively to this Advisory Committee meeting. (¶¶ 103-09.) “The Court may take judicial notice of materials available on government agency websites.” *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013) (taking judicial notice of documents “available on the FDA’s website”); *In re CV Therapeutics, Inc.*, 2004 WL 1753251, at *12 (N.D. Cal. Aug. 5, 2004) (taking judicial notice of full text of transcript and “FDA Briefing Materials” from FDA Cardiovascular and Renal Drugs Advisory Committee).

FibroGen Partner Press Releases. Finally, Defendants ask the Court to take judicial notice of press releases issued by AstraZeneca on December 20, 2018 and November 8, 2019 (Exs. F, Q) and by Astellas on August 20, 2021 (Ex. ZZ). Such press releases are publicly issued to the market, and judicial notice of such documents is appropriate for the limited purpose of determining what information was available to investors and the public, not the truth of the contents therein. *See In re Kalobios Pharms., Inc. Sec. Litig.*, 258 F. Supp. 3d 999, 1003 (N.D. Cal. June 23, 2017) (citing cases for proposition that third-party press releases and news articles is appropriate “in securities fraud cases to show that the market was aware of the information” contained therein).

IV. CONCLUSION

For the foregoing reasons, the Court should (1) consider Exhibits E, G, I-P, R-VV, and XX-YY to be incorporated by reference into the CAC; and (2) take judicial notice of Exhibits A-EEE.

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